> "As the present invention is a selection invention, wherein the specific material, i.e., polyamide, has been found to provide unexpected advantages not provided by other plastic materials, Applicants respectfully present that the selection of polyamide from among the list of possible materials would not have been obvious. The unexpected superior properties exhibited when polyamide is selected as the material for the spacer are demonstrated in the Affidavit under 37 CFR § 1.132, submitted Aug. 6, 2003."

Thus, as the declaration filed August 6, 2003 demonstrates that the selection of polyamide provides unexpected results, Applicants respectfully present that the selection of polyamide would not have been obvious to one of ordinary skill in the art at the time this invention was made. The Examiner has not disputed these results.

Moreover, even if Armer et al. teaches that a polyamide may be used, the Office Action fails to identify any motivation to one of ordinary skill in the art to select polyamide from among the laundry list provided in the cited passage.

B. "wherein the chamber ... comprises two frustoconical members assembled together coaxially at divergent ends"

The Office Action states that it would have been obvious to modify the device of Schmidt et al. to have the shape as taught by Berg et al, i.e., "two chambers that are assembled together coaxially at divergent ends," and to further modify the device such that the chambers are frustoconical in shape.

The device disclosed by Berg et al. comprises a chamber which is constructed from one "slightly conically tapering," and one "substantially hemispherical" member. Accordingly, the device of Berg et al., although being the closest cited prior art, contains, at best, only a single frustoconical member.

Moreover, even if Armer et al. teaches that a polyamide may be used, the Office Action fails to identify any motivation to one of ordinary skill in the art to select polyamide from among the laundry list provided in the cited passage.

As described herein, it is the applicants who found that there is an unexpected result which results from having a bi-frustoconical chamber, over the shapes of spacer chambers as shown in the cited art. The presently recited shape results in more efficient drug delivery than is

seen in devices with other shapes, such as the device as described by Berg et al. (marketed as "Nebuchamber").

The following experiments were conducted to determine the fine particle dose (fpd), the % maximal dose and the ex-device dose delivered by a pressurized metered dose inhaler (pMDI) used in conjunction with the spacer device of the present invention. This data can be directly compared with data for a pMDI used in conjunction with the Nebuchamber device, as described by Berg et al. (European Respiratory Journal (1998); 12:472-6), a copy of which is provided as herewith.

The experiments were performed with Budensonide 200 CFC inhaler. Results were collected using an eight stage Impactor (manufactured by Copley Scientific), used in accordance with the specifications laid down in the European Pharmacopeia, chapter 2.9.18. The Cascade Impactor is design for measuring the fine particle dose and size of an aerosol cloud generated by metered dose inhalers (MDIs) and dry powder inhalers (DPIs): as the aerosol stream passes through each stage of the Impactor, particles having large enough inertia will impact upon that particular stage plate, while the smaller particles will pass to the next impaction stage. By analyzing the amount of drug deposited on the various stages, the fine particle dose can be calculated. Fine particles are defined as having a particle size below 4.7 microns; fine particle dose provides an *in vitro* estimation for the amount of inhaled particulate drug reaching the target site, i.e., the lungs and lower airways of the respiratory tract.

The following tables show the data for the devices:

Comparative Dosing Data

Dose	Nebuchamber	Presently Claimed Device
Delivered dose (% of nominal dose)	89	80
Maximal dose (% of delivered dose)	55	68

Particle Size Distribution (Expressed as a percentage of maximal dose)

Particle Size	Nebuchamber (% of maximal dose)	Presently Claimed Device (% of maximal dose)
< 4.7 microns	68%	80%
< 3.3 microns	36%	65%
< 2.1 microns	9%	33%

This data shows that the bi-frustoconical device of the present invention delivers a fine particle dose which is superior to that which is delivered by the device of the prior art. The data shows that the % maximal dose (ex-device) for a spacer device according to the present claims is greater than that which is delivered by the device of the prior art. The % maximal dose below 4.7 microns is 80% for the device according to the present claims, compared to 68% for Nebuchamber. This indicates that when using the device of the prior art, there will be greater (undesirable) deposition of medicament particles in the oropharangeal region and upper airways than with use of the device of the present invention.

The proportion of particles below both 3.3 and 2.1 microns is substantially higher for the device of the present invention than for the prior art device, which indicates that a greater proportion of the medicament is present as particles small enough to penetrate the lower airways of the respiratory tract. Accordingly, there is a significant advantage in using a spacer device as presently claimed, which advantage would not be present in a device resulting from the combined teachings of Schmidt et al., Armer et al. and Berg et al.

II. Claim 7

Claim 7 stands rejected under 35 USC 103 as allegedly being unpatentable over Schmidt et al. in view of Hallworth et al. (U.S. Patent No. 4,206, 758). The Office Action asserts Schmidt et al. teaches each feature of the rejected claim, except for a locking means to lock the two members together, for which purpose Hallworth et al. is cited. Reconsideration is respectfully requested.

Even if Hallworth et al. teaches a locking means, such locking means is for locking together two halves of a medicament-containing capsule shell (column 5, lines 55-56), rather than locking means to lock together in an assembled condition two members forming a chamber. Hallworth et al. does refer to two chamber-forming members having a peg and a slot respectively, the peg being arranged in the slot and allowing axial movement, in a constrained spiraling path, of one chamber-forming member, with respect to other. As the members are relatively rotatable, they are not locked together in an assembled condition, as recited by claim 7. Nowhere in Hallworth et al. is this peg-slot combination described as being a locking means. Moreover, Hallworth et al. fails to teach or suggest the bi-frustoconical shaped features missing from Schmidt et al., as detailed above.

III. Conclusion

Reconsideration of the rejections is respectfully requested.

In view of the above, it is respectfully submitted that all objections and rejections are overcome. Thus, a Notice of Allowance is respectfully requested. If any additional fee is necessary, it may be charged to the undersigned's deposit account number 19-4375.

Respectfully submitted,

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